



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0530]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Tropical Disease Priority Review Vouchers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-New and title "Guidance for Industry on Tropical Disease Priority Review Vouchers." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry on Tropical Disease Priority Review Vouchers--

OMB Control Number 0910-NEW

Section 1102 of the Food and Drug Administration Amendments Act (FDAAA) adds new section 524 to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360n). Section 524 is designed to encourage development of new drug or biological products for prevention and treatment of certain tropical diseases affecting millions of people throughout the world and makes provisions for awarding priority review vouchers for future applications to sponsors of tropical disease products. By enacting section 524, Congress intended to stimulate new drug development for drugs to treat certain tropical diseases for which there are no or few available treatments by offering additional incentives for obtaining FDA approval for pharmaceutical treatments for these diseases. Under section 524, a sponsor of a human drug application for a qualified tropical disease may be eligible for a voucher that can be used to obtain a priority review for any application submitted under section 505(b)(1) of the FD&C Act (21 U.S.C. 355(b)(1)) or section 351 of the Public Health Service Act (the PHS Act). The guidance explains to internal and external stakeholders how FDA intends to implement the provisions of section 524, and provides information on using the priority review vouchers and on transferring priority review vouchers to other sponsors.

Under the guidance, sponsors of certain tropical disease drug product applications submitted under section 505(b)(1) of the FD&C Act and section 351 of the PHS Act may request a priority review voucher. Based on inquiries and discussions with industry about section 524, we estimate that we will receive annually approximately five requests from five sponsors, and that each request will take approximately 8 hours to prepare and submit to FDA.

The guidance also states that sponsors should notify FDA of their intent to use a priority review voucher, including the date on which the sponsor intends to submit the application, at least 90 days before use. We estimate that we will receive annually approximately five notifications of intent to use a voucher from five sponsors, and that each notification will take approximately 8 hours to prepare and submit to FDA.

The guidance also permits the transfer of a priority review voucher from one sponsor to another, and states that each transfer should be documented with a letter of transfer. We estimate that we will receive approximately two letters indicating the transfer of a voucher from two application holders, and two letters from two new voucher owners acknowledging the transfer, and that it will take approximately 8 hours to prepare and submit each letter to FDA.

In the Federal Register of October 20, 2008 (73 FR 62298), FDA published a 60-day notice requesting public comment on the proposed collection of information. The comments we received did not pertain to the information collection that would result from the guidance (that is, the four types of submissions estimated in table 1).

FDA estimates the burden of this collection of information as follows:

Description of Respondents: Sponsors submitting applications under section 505(b)(1) of the FD&C Act or section 351 of the PHS Act.

Table 1.--Estimated Annual Reporting Burden¹

Guidance for Industry on Tropical Disease Priority Review Vouchers	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Priority Review Voucher Request	5	1	5	8	40
Notifications of Intent To Use a Voucher	5	1	5	8	40
Letters Indicating the Transfer of a Voucher Letter	2	1	2	8	16
Acknowledging the Receipt of a Transferred Voucher	2	1	2	8	16
Total					112

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: November 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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